IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

THE ROCKEFELLER UNIVERSITY and CHIRON CORPORATION, Plaintiffs,	§	
v.	§	CIVIL ACTION NO. 2:04-CV-168 (TJW)
CENTOCOR, INC. and ABBOTT LABORATORIES, Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court are two Motions for Summary Judgment filed by Defendant Abbott Laboratories ("Abbott") based on separate Federal Circuit cases – the first, *Noele v. Lederman* (#92); the second, *Chiron v. Genentech* (#93). The Court has carefully considered the parties' written submissions and hereby denies Abbott's Motion based on *Noele v. Lederman* and carries with the case Abbott's Motion based on *Chiron v. Genentech*.

I. Introduction

In 2004, Plaintiffs The Rockefeller University ("Rockefeller") and Chiron Corporation ("Chiron") filed suit against Abbott alleging that Abott's Humira product infringed various claims of U.S. Patents 6,419,927 ("the '927 patent") and 6,309,640 ("the '640 patent") (collectively "the Patents"). The Patents both claim priority, through a series of continuation applications, to patent application No. 06/792,372 ("the '372 application"), filed on September 7, 1982. The Patents share a substantially identical specification, which is also substantially identical to the specification from the '372 application.

A detailed description of the technology has been set forth in the Court's claim construction ruling of October 30, 2005 and is incorporated herein. The asserted claims of the Patents are directed to the therapeutic use of an antibody to a substance the patents define as "about 70 kDa mediator substance." This Court construed the "about 70 kDa mediator substance" to mean "biologically active TNFα." This construction would necessarily cover antibodies to TNF from any species, including humans. Defendant Abbott moves for summary judgment under *Noele* because the Patents allegedly violate 35 U.S.C. § 112 for failing to disclose a human protein when all that is described in the specification is a mouse protein.

II. Motion for Summary Judgment Under *Noele v. Lederman*

In *Noele v. Lederman*, the Federal Circuit held that the specification in a parent patent application for murine antibodies did not satisfy the written description requirement for subsequent application's with human and genus antibody claims. *Noele v. Lederman*, 335 F.3d 1343 (Fed. Cir. 2004). Abbott asserts that *Noele* is black-letter law that a description of a mouse protein is not a description of a human protein. Abott is incorrect and its motion for summary judgment must be denied.

"[S]ummary judgment is as appropriate in a patent case as in any other." *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc*., 853 F.2d 1557, 1561 (Fed. Cir. 1988). The moving party is entitled to summary judgment when there is not a genuine issue as to any material fact and the moving party is entitled to to a judgment as a matter of law. Fed. R. Civ. P. 56(c); *Telemac Cellular Corp. v. Topp Telecom, Inc*., 247 F.3d 1316 (Fed. Cir. 2001). However, in ruling on a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 255 (1986).

Moreover, in deciding Abbott's motion, this Court must view the evidence presented "through the prism of the substantive evidentiary burden" at trial. *Id*. at 254. Here, Abbott seeks to invalidate two patents. "[A] patent enjoys a presumption of validity which can be overcome only by clear and convincing evidence." *Eli Lilly & Co. v. Barr Labs., Inc*., 251 F.3d 955, 962 (Fed. Cir. 2001). Thus, Abbott must prove invalidity in its summary judgment motions by a clear and convincing standard.

This standard contrasts sharply with the standard applied in *Noele*. *Noele* was an appeal of a decision in an interference proceeding by the United States Patent and Trademark Office, Board of Patent Appeals and Interferences (the "PTO Board"). *Noele v. Lederman*, 335 F.3d 1343 (Fed. Cir. 2004). The applicable standard of review was the substantial evidence standard, under which the Federal Circuit ***must*** uphold the PTO Board's decision as long as a "reasonable fact finder could have arrived at the agency's decision." *Id*. at 1348 (*citing In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000)). Under that standard, "[t]he possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Id*. Accordingly, *Noele* reflects only that there was substantial evidence that supported the PTO Board's decision that the written description requirement was not satisfied, although there could also have been substantial evidence to the contrary that the written description requirement was satisfied. Here, summary judgment is appropriate only if Abbott demonstrates that there are no genuine litigable issues and that Plaintiffs' evidence would not allow a reasonable jury, applying the clear and convincing evidentiary standard, to conclude that the Patents are valid. Thus, from an evidentiary perspective, reliance solely on *Noele* to support summary judgment is questionable at best. However, notwithstanding *Noele's* questionable application in this case, the Court will address

Abbott's substantive complaints regarding compliance with 35 U.S.C. § 112.

Whether a specification complies with the written description requirement of 35 U.S.C. § 112, ¶ 1, is a question of fact. *Noele*, 355 F.3d at 1348 (*citing Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991). A patent's specification's compliance with the written description requirement turns on whether the specification would "allow persons of ordinary skill in the art to recognize that [the patentee] invented what is claimed." *Vas-Cath*, 935 F.2d at 1563. The inquiry "depends on the nature of the invention and the amount of knowledge imparted to those of skill in the art by the disclosure." *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 996 (Fed. Cir. 2000). Thus, "consideration of what the [disclosure] conveyed to persons of ordinary skill is essential." *Vas-Cath*, 935 F.2d at 1566.

Abbott's assertion that the finding in *Noele ipso facto* warrants summary judgment in this case is belied by the very opinion itself. The Federal Circuit in *Noele* cautioned that issues involving written description "must be decided on its own facts" and that "the precedential value of cases in this area is extremely limited." *Noele*, 355 F.3d at 1349 (*citing Vas-Cath*, 935 F.2d 1555, 1562). Thus, Abbott is entitled to summary judgment under *Noele* and pursuant to 35 U.S.C. § 112, ¶ 1 ***only if*** there are no genuine issues of material fact regarding the sufficiency of the written description of the Patents. Based on the summary judgment record, and assuming that all facts are to be construed in favor of the non-movant, Abbott's motion must be denied.

First, the Patents themselves clearly contemplate and discuss the use of mammalian antibodies, and more specifically, human antibodies. For example, the specification states:

> [W]e have discovered an agent which we identify herein as a mediator substance, that is produced by ***mammalian cells*** in response to stimulation by materials we refer to herein as stimulator materials . . . . We have observed that the mediator substance

> causes the metabolism of certain cells ***of the mammal*** to switch from anabolic state to a catabolic state . . . .

('640 patent 7:39-65) (emphasis added).[1] In short, the specification leaves no doubt that the invention of the Patents is not limited to combating the effects of the "mediator" produced in a mouse.

Normally, this Court is faced with affidavits and various sources of proof from a defendant seeking summary judgment. Abbott has instead chosen to rely almost exclusively on the decision in *Noele* to establish summary judgment. Accordingly, to survive summary judgment based on 35 U.S.C. § 112, ¶ 1, Plaintiffs need only offer competent proof establishing a genuine dispute of material fact regarding how one of ordinary skill in the art would have viewed the disclosure. In this case, a scintilla of evidence would warrant denial of summary judgment, but Plaintiffs have offered far more.

Plaintiffs' expert Dr. Charles Dinarello states that the Patents' description of making TNF by "obtaining macrophage cells from mammals" could be accomplished using cells from humans and other mammals (not just mice). Describing a substance by the process of making it, even without disclosing its structure, has been held to satisfy the written description requirement. *In re Edwards*, 568 F.2d 1349, 1352 (C.C.P.A. 1978).

Dr. Dinarello also opines that at the time of the September 1982 priority application underlying the Patents, most cytokines had been determined to have biological activity in assays

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[1] The specification is replete with references to the "mediator substance" in mammals. The "Background of the Invention" describes the context of the invention in terms of biochemical derangements seen in "various mammalian hosts" (1:47), noting examples in rabbits and humans (1:46-2:14). Similarly, the "Summary of the Invention" speaks of "a method for preparing a mediator fur use in assessing the state of anabolic enzymes in mammals . . . which finds particular utility in the instance where the mammals are undergoing invasive stimuli . . . ." (2:43-47). There are numerous other examples in the specification to mammals, which is broader than the single mouse species Abbott asserts now.

using cells from a different mammal, and that "[t]he use of cross-species assays was routine when investigating cytokine activity." Further, Dr. Dinarello concludes, based on the disclosure of the specification of the Patents and the knowledge in the art regarding other cytokines, that "[i]n September 1982, a person skilled in the art would have expected that the characteristics describing the about 70 kDa fraction that is obtained from LPS stimulated macrophage cells and that suppresses LPL activity in the Cerami Patents generically to have described the mediator in mammals and to have described the mediator in humans." Dr. Dinarello addresses each feature identified by the patents as characterizing TNF and finds them applicable not only to murine TNF, but also to other mammalian forms of TNF, including human.

Dr. Dinarello's testimony, which must be accepted as true for purposes of Abbott's motion, pertains specifically to TNF and the particular biological properties by which the patent characterizes mammalian TNF. As Dr. Dinarello testified at his January 3, 2006 deposition in this case:

> "You would not have to do human experiments to know the properties of human TNF at that time. The reason is the mouse and all the cytokines had cross-species relationships. . . One of the properties of cytokines was cross-species. And so you could make a lot of conclusions if you had purifies mouse TNF and showed it had suppression of LPL activity and assume pretty much . . . that it was the same thing if you isolated TNF from human cells and did the same assay, even on mouse cells."

In summary, Abbott misplaces the efficacy of *Noele* and fails to offer much, if any, proof that would warrant summary judgment in its favor. Plaintiffs, on the other hand, offer voluminous amounts of competent summary judgement evidence that a finder of fact could rely on in determining that Plaintiffs' Patents are valid. Accordingly, Abbott's Motion for Summary Judgement Based on *Noele v. Lederman* is denied.

SIGNED this 13th day of June, 2006.

T. JOHN WARD
UNITED STATES DISTRICT JUDGE